UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

LISA D. CARPENTER and JEFFREY D. CARPENTER, Plaintiffs, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 1:14-cv-00540-AJ

Joint Discovery Plan
Under Rule 26(f) of the Federal Rules of Civil Procedure

Date/Place of Conference: Counsel for the parties conferred by telephone on February 2, 2015.

Counsel Present/Representing: R. Brent Wisner of Baum Hedlund Aristei & Goldman PC represented Lisa D. Carpenter and Jeffrey D. Carpenter. Phyllis A. Jones of Covington & Burling LLP represented Eli Lilly and Company.

Case Summary

Theory of Liability: This lawsuit centers on a phenomena called withdrawal—the physical and mental effects patients suffer from upon discontinuing the drug Cymbalta. The physical effects patients experience upon stopping Cymbalta mirror those of a narcotic: dizziness, headaches, nausea, diarrhea, excessive sweating, sensory disturbances, nightmares, and insomnia. However, in addition to these effects, patients stopping Cymbalta also experience side effects unique to antidepressants: electronic shock sensations in the brain, loss of motor functions, seizures, extreme mood swings, emergence of depression, emotional outbursts, and suicidal behavior / attempts.

Defendant Eli Lilly and Company ("Lilly") manufactures and sells Cymbalta. Plaintiffs allege that in the marketing of Cymbalta, Lilly failed to adequately warn patients about the frequency, severity, and duration of Cymbalta withdrawal. Specifically, the Cymbalta label suggests that the frequency of withdrawal is rare, stating that withdrawal reactions occur "at a rate greater than or equal to 1%." And yet, Lilly's *own* clinical trials show that the risk of suffering from withdrawal is at least 45% and likely much higher. In addition, nowhere in the label does it indicate the severity of withdrawal, even though Lilly's trials show that 9-17% of withdrawal is severe and over half is moderate. The Cymbalta label also does not indicate the likely duration of withdrawal, even though Lilly knew that over half of people who suffer from withdrawal last longer than two weeks.[1] In addition, Plaintiffs allege that the Cymbalta drug is not designed safely because, due to the unique properties of the Cymbalta capsule, it is impossible to gradually taper off the medication. As a result of this alleged failure-to-warn and design defect, Plaintiff Lisa Carpenter suffered serious withdrawal effects from stopping Cymbalta that she would not have experienced if she had been properly warned or had the Cymbalta pill been properly designed.

Theory of Defense: Since 2004, the FDA-approved package insert for Cymbalta has included a detailed, three-paragraph warning on the potential risk of symptoms upon discontinuation of Cymbalta treatment. Lilly maintains that the Cymbalta discontinuation warning is adequate as a matter of law, *McDowell v. Eli Lilly and Co.*, -- F. Supp. 3d ---, No. 13-3786, 2014 WL 5801604, at **10-15 (S.D.N.Y. Nov. 7, 2014) (ruling that Cymbalta discontinuation warning is adequate as a matter of law), and that Plaintiffs cannot establish that any alleged inadequacy in the

[1] By way of contrast, the European label contains the 45% warning, states that withdrawal may last up to 2 to 3 months, and that tapering should be done over no less than two weeks—warnings that are all absent from the U.S. label.

warning was the cause of Plaintiffs' alleged injuries. *See McDowell*, 2014 WL 5801604 at *15; *Carnes v. Eli Lilly and Co.*, 2013 WL 6622915 at *7 (D.S.C. Dec. 16, 2013).

Damages: Plaintiffs allege damages in excess of $75,000 physical, emotional, and psychological injuries, past and future pain and suffering and mental anguish, loss of enjoyment of life, past and future medical expenses, and loss of consortium and companionship.

Demand: Due no later than January 26, 2016.

Offer: Due no later than February 16, 2016.

Jurisdictional Questions: There is no disagreement regarding the existence of federal jurisdiction.

Questions of Law: *See* Theory of Liability and Theory of Defense.

Type of Trial: Jury trial.

Discovery

Track Assignment: Standard – 12 months for fact discovery.

Discovery Needed: Discovery will be conducted on the allegations in the Complaint and the defenses in the Answer, including discovery on the Plaintiffs' claimed injuries, medical conditions, and alleged damages, Defendant's liability, and general and case-specific causation.

Mandatory Disclosures [Fed. R. Civ. P. 26(a)(1)]: Pursuant to agreement, Defendant produced its initial disclosures on January 22, 2015, and Plaintiffs shall produce their initial disclosures by February 9, 2015.

Electronic Record Disclosures [Fed. R. Civ. P. 26(f)]: The parties will comply with all local and federal rules regarding electronic discovery. At this time, there do not appear to be any special issues related to the disclosure or discovery of electronically stored information ("ESI"). The parties reserve the right to identify issues that may arise related to disclosures or discovery

of ESI and anticipate that a mutually agreed-upon stipulation governing the discovery of ESI will be entered.

Stipulation Regarding Claims of Privilege/Protection of Trial Preparation Materials: Fed. R. Civ. P. 26(b)(5) and Fed. R. Evid. 502 shall apply.

Completion of Discovery: Fact discovery shall be completed by February 26, 2016. Expert discovery shall be completed by June 25, 2016.

Interrogatories: A maximum of 25 interrogatories by each party to any other party. Responses are due 30 days after service unless otherwise agreed to pursuant to Fed. R. Civ. P. 29.

Requests for Admission: The parties were unable to reach agreement on the maximum number of requests for admission by each party to any other party. Plaintiffs propose a maximum of 60 and Defendant proposes a maximum of 25 requests for admission by each party to any other party. Responses are due 30 days after service unless otherwise agreed to pursuant to Fed. R. Civ. P. 29.

Depositions: A maximum of 10 depositions of fact witnesses by each party. Each deposition shall be limited to 7 hours unless extended by agreement of the parties or order of the Court.

Dates of Disclosure of Experts and Experts Written Reports and Supplementation:

Plaintiff: March 22, 2016

Defendant: April 22, 2016

Challenges to Expert Testimony: September 9, 2016

Other Items

Disclosure of Claims against Unnamed Parties: April 2, 2015

Joinder of Additional Parties: May 2, 2015

Third Party Actions: May 2, 2015

Amendment of Pleadings: May 2, 2015

Summary Judgment Motions: June 24, 2016

Settlement Possibilities: Settlement possibilities are not known at this time.

Joint Statement Re: Mediation: Mediation, if any, will occur by October 10, 2016.

Witnesses and Exhibits: Ten (10) days before the final pretrial conference but not less than 30 days before trial for lists (included in final pretrial statements) and 14 days after service of final pretrial statement for objections – set by Clerk's Notice of Trial Assignment.

Trial Estimate: 5-10 days.

Trial Date: Beginning the week of October 24, 2016, as the Court's calendar permits.

Other Matters: None at this time.

Respectfully submitted,

LISA D. CARPENTER and
JEFFREY D. CARPENTER,

By their attorneys,

Dated: February 6, 2015

/s/ Leslie C. Nixon
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ELI LILLY and COMPANY

By its attorneys,

Dated: February 6, 2015

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Certificate of Service

I hereby certify that on this 6th day of February, 2015, the foregoing Joint Discovery Plan was filed using the CM/ECF system, which will send notification of the filing to all parties that have appeared in this action.

/s/ Michele E. Kenney
Michele E. Kenney